Conclusions: Whilst GpIIb/IIIa inhibitor use was associated with a significant protective effect on Kaplan–Meier survival analysis, this disappeared when the significant baseline disparities seen in these patients were accounted for.

TCT-140

Prospective Multicenter Registry of 6 Months Dual Antiplatelet Therapy after new Generation Drug-eluting Stent Implantation: ESTROFA-DAPT Study.

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Background: Drug-eluting stents (DES) have been related to a certain risk of late thrombosis. The recommended duration of dual antiplatelet therapy (DAPT) with DES is 12 months. DAPT is not free from complications and is expensive. Trials with limited size suggest that a 6 month DAPT period could be enough with new generation DES. There are no prospective clinical registries assessing the safety of such approach.
Methods: All consecutive patients treated with a new generation DES (Xience V, Xience Prime, Endeavor Resolute, Promus Element, Biomatrix, Nobori, Osiro) were prospectively included in 20 different centers. Patients had to fulfill one of the following inclusion criteria in order to have 6 month DAPT period prescribed: silent ischemia, stable angina, low risk non-ST segment elevation myocardial infarction or acute coronary syndrome where 12 months DAPT was discarded due to high bleeding risk. Taking advantage of the ESTROFA-2 database (4,768 patients treated with new generation DES, 4355 of them with 12 months DAPT) we will perform a propensity score matching of the six months DAPT from the ESTROFA-DAPT registry with the 12 months DAPT from the ESTROFA-2 registry.
Results: A total of 800 patients have been included so far in 20 centers. The baseline characteristics of the matched groups and the 1 year follow up results of the first 500 patients would be presented at the meeting sessions.
Conclusions: The ESTROFA-DAPT registry will provide data regarding safety of a 6 month DAPT period after new generation DES implantation.

TCT-141

The Disutility of Nuisance Bleeding: Insights from the TRANSLATE ACS Registry

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Background: Prolonged dual anti-platelet therapy (DAPT) is recommended after an acute coronary syndrome (ACS) to reduce ischemic events, but is associated with increased rates of major and minor bleeding. The incidence of even lesser degrees of 'nuisance' bleeding on DAPT and its impact on quality of life (QOL) are largely unknown.
Methods: We studied 9290 ACS patients from the TRANSLATE ACS study who were treated with PCI and discharged alive between April 2010 to Sept 2012. Bleeding post-hospital discharge was defined via the BARC bleeding definitions. Our primary outcome was the 6 month EQ-5D™ index score, based on the U.S. population preference weights. The EQ5D visual analog scale (VAS) at 6 months was a secondary outcome. To determine the association between nuisance bleeding and 6-month QOL, we fit a mixed-effects linear regression model for 6 month EQ5D index adjusting for baseline EQ5D index, with site as random effect (hierarchical model) and other confounders of the relationship between bleeding and health status. We fit a similar model for EQ5D visual analog scale (VAS).
Results: Of the 9,290 patients with ACS (mean age 61, 73% males, 89% Whites), 4134 (44.5%) underwent immediate PCI for STEMI, and 4308 (46.4%) underwent PCI for non-STEMI. A total of 849 (9.1%) patients experienced BARC I type nuisance bleeding. Those who experienced BARC I bleeding had lower scores on all 5 EQ5D domains (mobility, self-care, usual activities, pain and anxiety) and had a lower 5 point EQ5D VAS score. After adjustment for confounders, nuisance bleeding by 6 month was independently associated with a decrement in QOL at 6 month (-2.04 points on EQ5D VAS; 95% CI -0.93 to -3.15, P<0.001). Based on the EQ5D index score, the utility decrement associated with nuisance bleeding was 0.026, 95% CI 0.015 to 0.037, P-value <0.001.
Conclusions: In TRANSLATE-ACS, we found that BARC Type I (nuisance) bleeding occurred in 1 of 10 patients after an ACS event and was associated with worse 6-month quality of life and utility. These findings suggest that even nuisance bleeds are relevant to patients and deserve greater attention in clinical recommendations for treatment and future clinical trials of prolonged DAPT therapies.

TCT-142

Prasugrel 5 mg inhibits platelet GPIIb-IIIa and P-Selectin expression in the very elderly - Results from the GENERATIONS trial, a pharmacodynamic study in stable CAD patients

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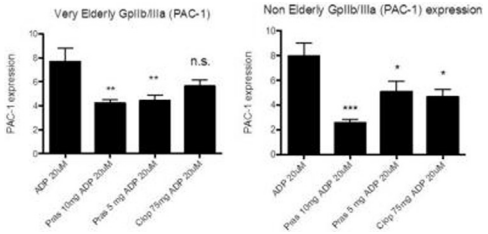
Background: Platelet surface P-selectin and activated GPIIb-IIIa are markers of platelet activation, degranulation and aggregation. In the TRITON trial prasugrel (Pras) 10 mg reduced ischemic events vs. clopidogrel (Clop) 75 mg but increased bleeding, notably in very elderly (VE) patients. Pras 5 mg is a treatment option in VE patients but data on its effect on GPIIb-IIIa and P-selectin expression is lacking. We performed a blinded, three-period cross-over study in stable CAD patients ≥75 y (VE) or 45-65 y (NE) examining expression of these biomarkers following Pras (5 or 10 mg) and Clop 75 mg.
Methods: After a run-in on low dose aspirin, VE subjects (n=23, 78 ± 5 y) and NE subjects (n=22, 55 ± 5 y) were randomized to Pras (5 or 10 mg) or Clop 75 mg during three 12-day periods. ADP (20 μM)-stimulated platelet P-selectin and GPIIb-IIIa (PAC-1) were measured by flow-cytometry at baseline and at the end of each12-day dosing period.
Results: PAC-1 and P-selectin (data not shown) expression after stimulation with 20 μM ADP did not differ between VE and NE at baseline or after any treatment period (Figure). PAC-1 expression was significantly reduced by pras 5 mg in both VE (p<0.01) and NE (p<0.05). In the VE the 5 mg dose had similar effect as pras 10 mg. Clop 75 mg did not significantly reduce PAC-1 in VE. P-selectin expression showed a similar profile (data not shown).



Conclusions: As assessed by GPIIb-IIIa and P-selectin in stable CAD patients, Pras 5 mg significantly reduced ADP-induced platelet activation in the VE.

TCT-143

Twelve-Month Clinical Outcomes from the Optimal Duration of Dual Antiplatelet Therapy Following Treatment with Endeavor (Zotarolimus-Eluting Stent) in Real-World Japanese Patients with Coronary Artery Disease (OPERA) Study

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Background: Increasingly cardiologists need to place coronary artery disease patients implanted with drug-eluting stents on dual antiplatelet therapy (DAPT) regimens of durations shorter than the 6-12 months recommended in current guidelines. Unfortunately, no sufficient clinical data are available to support such shorter DAPT durations.
Methods: This prospective, nonrandomized, multicenter, controlled study of the Endeavor zotarolimus-eluting stent (E-ZES) in real world Japanese patients consists of two arms: patients who were enrolled at 106 medical institutions to receive DAPT for 3 months and then followed for 1year, and a 12-month DAPT arm consisting of patients consecutively extracted from patients enrolled in the Endeavor Japan post-marketing surveillance. The analysis was done on an intent to treat basis. The

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